ZEE AMERICA'S WORKPLACE SAFETY EXPERT.™

May 13, 1999

Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

APPLICATION FOR EXEMPTION

Re: Request for Exemption from 21 CFR 201.66 (OTC Labeling Format)
Docket Number 98N-0337

Subject: Zee Medical, Inc.
#614 Tetrahydrozoline Eye Drops

This is a request for exemption from certain requirements of 21 CFR 201.66 (OTC Labeling Format), for Zee Medical, Inc. Tetrahydrozoline Eye Drops. We believe these requirements are impracticable for this product due to the small package size, our method of distribution, the method of final use of the product by numerous users, and other factors as outlined below.

Overview of Zee Medical, Inc.

Zee Medical, Inc. is a wholesale distributor of first aid and safety products. We provide these products to independent distributors and company-owned distributors who in turn sell them to employers for use in the employers' workplace first aid cabinets. These products are delivered to the employer by means of a van-based delivery system. The first aid items are placed directly into the first aid cabinet by the Zee sales representative and are prepared for immediate use.

Description of Product

Zee Tetrahydrozoline Eye Drops (#614) is a sterile OTC ophthalmic product packaged in 0.5 fluid ounce bottles. The product is manufactured by an outside supplier who provides it to us in private-labeled bottles silk screened with the Zee Medical label. The bottle also has a tamper-evident shrink band. The finished bottles are packaged into shipping cartons, 72 bottles per shipping carton. No further packaging is done.

Distribution and Use

We provide the Eye Drops to our distributors in one of two ways: (1) we package the individual bottles into first aid kits, which are sold to our distributors, or (2) we provide the Eye Drops to our distributors in the original shipping cartons, to be used as replenishment for first aid cabinets in the workplace. The end result is that the Eye Drops become a component of a workplace first aid cabinet shared by many employees.

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Zee Medical, Inc. McKesson Corp. • 22 Corporate Park • Irvine, CA 92606 • (949) 252-9500 • Fax: (949) 252-9649

Exemption Request

We are requesting exemption for this product from some of the format and font size requirements of 21 CFR 201.66. Under the conditions described above, we believe it is imperative that the full labeling be (1) an integral part of the immediate package and (2) available to all individuals throughout the life of the product. Since our method of delivery to the user is not a typical retail application, we believe that the usual methods of conveying labeling information to the user are not appropriate for this product. This includes any packaging component which may be discarded, including a larger outside package (i.e., a box), a package insert, or a foldout booklet on the bottle itself. Our concern is that such labeling may be read by the first person or two that uses the product, but it will then become separated from the product and discarded, thereby denying all other users access to the information. If the full labeling is not available to the user, our company will be exposed to the possibility of product liability claims due to our failure to properly warn the user.

We have evaluated other forms of packaging for this product, including a larger bottle size and disposable unit dose packaging. Both of these packaging configurations were rejected by our distributors and by their customers due to their awkward size and higher cost. We have concluded that neither of these options is a viable alternative for use in workplace first aid cabinets. If this exemption is not granted, we will either have to discontinue the product or provide it in a retail box, which we know will be discarded.

We are proposing to use a modified version of the labeling format specified in 21 CFR 201.66. A copy of our proposed labeling for this product is enclosed. The Drug Facts heading shown on the back panel of the proposed label is 7-point type, the headings are 6-point, and the text is 4.5-point. Because these products are sold exclusively to employers for use in the workplace, the age profile of users of this product is much narrower and much younger than that of the general adult population. According to Bureau of Labor Statistics figures (1998, 4th quarter) only 1% of full-time workers are over the age of 64 and only 10% are over the age of 54. The type size on the current product label is 4-point. Over the past ten years we have not received a single documented customer complaint concerning the small type size of this product. Given these circumstances, we believe that a type size of 4.5-point, as recommended by NDMA, is an appropriate minimum type size for this product.

We appreciate your consideration of this request and look forward to receiving your response as soon as possible. If you need additional information or would like to discuss this matter in person, please call me directly at (949) 252-9530.

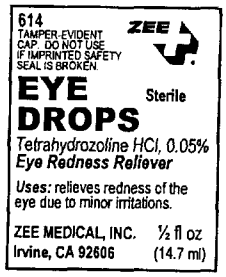
Very truly yours,

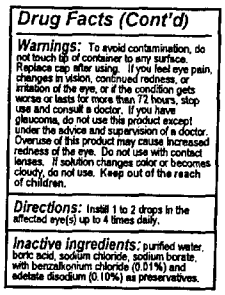
Kevin Lloyd
Manager, Quality and Regulatory Affairs
Zee Medical, Inc.

Enclosure

Proposed Label Copy for Zee #614 Eye Drops

Actual Size





Enlarged

614
TAMPER-EVIDENT
CAP. DO NOT USE
IF IMPRINTED SAFETY
SEAL IS BROKEN.

ZEE

EYE Sterile
DROPS

Tetrahydrozoline HCl, 0.05%
Eye Redness Reliever

Uses: relieves redness of the eye due to minor irritations.

ZEE MEDICAL, INC. ½ fl oz
Irvine, CA 92606 (14.7 ml)

Drug Facts (Cont'd)

Warnings: To avoid contamination, do not touch tip of container to any surface. Replace cap after using. If you feel eye pain, changes in vision, continued redness, or irritation of the eye, or if the condition gets worse or lasts for more than 72 hours, stop use and consult a doctor. If you have glaucoma, do not use this product except under the advice and supervision of a doctor. Overuse of this product may cause increased redness of the eye. Do not use with contact lenses. If solution changes color or becomes cloudy, do not use. **Keep out of the reach of children.**

Directions: Instill 1 to 2 drops in the affected eye(s) up to 4 times daily.

Inactive ingredients: purified water, boric acid, sodium chloride, sodium borate, with benzalkonium chloride (0.01%) and edetate disodium (0.10%) as preservatives.

Font Sizes:

Drug Facts	***7 point, bold italic***
Headings:	***6 point, bold italic***
Back Panel Text	4.5 point

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Zee Medical, Inc. McKesson Corp.
22 Corporate Park, Irvine, CA 92606

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